

D2 characteristic of antibody-antigen, specific binding protein-receptor and enzyme substrate associations, the prosthesis having a valve structure.

REMARKS

Claims 1-11, 14,15 and 21-28 remain for consideration. Applicants have amended claims 1 and 14 to more distinctly point out the invention. Support for the amendments is found, for example, in the Specification on page 14, lines 23-26.

Rejection over Guire

The Examiner rejected claims 1-4 and 11 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,263,992 to Guire et al. (The Guire patent). The Examiner indicated that the Guire patent discloses an allograft tissue and that growth factors in the Guire patent are bound covalently with a linker molecule.

Applicants submit that amended claim 1 and dependent claims 2-4 and 11 in the present invention are not anticipated by the Guire patent. The disclosure in the Guire patent relates to covalently bonding the growth factors using externally activated linker molecules that are limited to surface adhesion, i.e. photochemical and thermochemical groups on the linker molecules. These linker molecules of the Guire patent remain on the solid surface and do not penetrate into tissue as the crosslinking agents in the present invention. Crosslinking agents are difunctional compounds in which each functional group reacts with a component of tissue, generally protein, and are incorporated into tissue. The linker molecules of the Guire patent do not have functional groups that react with tissue

without external activation. Amended claim 1 indicates that crosslinking agents are used for covalently bonding the growth factors with the tissue in the present invention. Furthermore, the crosslinking agents do not need external activation like the linker molecules of the Guire patent.

Since the Guire patent does not disclose the claimed invention, Applicants respectfully request the withdrawal of the rejection of claims 1-4 and 11 under 35 U.S.C. § 102(b) as being anticipated by the Guire patent.

Rejection over Guire in view of Carpentier

The Examiner rejected claims 5-8, 25, 27 and 28 under 35 U.S.C. 103(a) as being unpatentable over the Guire patent in view of U.S. Patent No. 4,648,881 to Carpentier et al. (The Carpentier patent).

The Examiner indicated that with respect to claims 5, 6, 25, 27 and 28, the Guire patent meets the claim language except for the use of crosslinked or uncrosslinked tissue as a base material. The Examiner stated that the Carpentier patent teaches to use either crosslinked or uncrosslinked tissue as an implant material. The Examiner concluded that it would have been obvious to use the crosslinked or uncrosslinked tissue in the Guire invention.

The Examiner indicated that with respect to claims 7, 8, 27 and 28 that the Guire patent meets the claim language but uses human tissue instead of porcine heart valve or bovine pericardial tissue as claimed. The Examiner indicated that the Carpentier patent teaches that it was known to the art to use porcine heart valve or bovine pericardial tissue. The Examiner

concluded that it would have been obvious to use either tissue for human tissue of the Guire patent.

The combination of the Guire patent and the Carpentier patent does not result in the claimed invention as recited in claims 5-8, 25, 27 and 28. With respect to claims 5-8, dependent on amended claim 1, there is no teaching or suggestion in the Guire patent related to use of crosslinking agents to covalently bond a growth factor to a prostheses. The Guire patent teaches using linker molecules with photochemical and thermochemical groups to attach a growth factor to a solid surface. As discussed above, these linker molecules are on the surface and do not incorporate into tissue. There is no teaching or suggestion in the Carpentier patent related to using crosslinking agents or other compounds to covalently bond growth factors to prosthesis. The combination of the Guire patent and the Carpentier patent, thus, does not teach or suggest attaching a growth factor to a prosthesis using crosslinking agents.

With respect to claims 25, 27 and 28, the combination of the Guire patent and the Carpentier patent does not teach or suggest the claimed invention. There is no discussion in the Guire patent related to attaching growth factors to crosslinked tissue. The Guire patent only discloses attaching growth factors to the surface, not incorporated into the tissue as in the present invention. The Guire patent merely provides a laundry list of solid surfaces that may be functional. See the Guire patent, col. 4, lines 2-24. This laundry list, however, does not include crosslinked tissue. Crosslinked tissue has specific properties different from the substrates in the Guire patent.

The Carpentier patent merely indicates the use of crosslinked tissue or uncrosslinked tissue as implantable material. The Carpentier patent, in fact, teaches away from the present invention since the Carpentier patent states that solutions used with the tissue should not react with the fixing agent or prevent the fixing agent from achieving proper fixation of the tissue. See the Carpentier patent, col. 4, lines 51-56. There is no discussion in Carpentier related to attaching a growth factor. Applicants assert that there is no teaching or suggestion of forming the asserted combination when the Guire patent and the Carpentier patent are combined. Furthermore, there is no reasonable expectation of success of the claimed invention when the Guire patent and the Carpentier patent are combined since the Carpentier patent teaches that solutions that contact tissue should not react with the fixing agent or interfere with proper tissue fixation.

Applicants submit that independent amended claim 1 and claim 25 are not obvious over the Guire patent in view of the Carpentier patent. The dependent claims 5-8, 27 and 28 are thus also not obvious in view of the cited art. Applicants respectfully request the withdrawal of the rejection of claims 5-8, 25, 27 and 28 under 35 U.S.C. § 103(a) as being unpatentable over the Guire patent in view of the Carpentier patent.

Rejection over Guire and Carpentier further in view of Tischer

The Examiner rejected claims 9, 10, 14, 15, 21-24 and 26 under 35 U.S.C. 103(a) as being unpatentable over the Guire patent and the Carpentier patent further in view of U.S. Patent No. 5,194,596 to Tischer et al. (The Tischer patent).

The Examiner indicated that the Guire patent discloses the use of various growth factors with the implant but fails to disclose the use of vascular endothelial growth factor. The Examiner stated that the Tischer patent teaches the use of vascular endothelial growth factor with implants. The Examiner concluded that it would have been obvious to use vascular endothelial growth factor as the growth factor.

The combination of the Guire patent, the Carpentier patent and the Tischer patent does not teach or suggest the invention claimed in claims 9, 10, amended claim 14, 15, 21-24, and 26. As discussed above, the combination of the Guire patent and the Carpentier patent does not teach or suggest covalently bonding a growth factor using crosslinking agents as claimed in amended claims 1 and 14. The Tischer patent does not provide any teaching that when combined with the Guire patent and the Carpentier patent results in the claimed invention. The Tischer patent merely teaches exposing a desired surface to a vascular endothelial growth factor by incubation but does not teach or suggest attachment of the vascular endothelial growth factor using crosslinking agents.

With respect to claim 26, there is no teaching or suggestion in any of the cited patents, alone or combined, that vascular endothelial growth factor can be attached to a prosthesis that includes crosslinked tissue. As discussed above, the Guire patent merely provides a laundry list of solid surfaces that may be functional. See the Guire patent, col. 4, lines 2-24. This laundry list, however, does not include crosslinked tissue. Crosslinked tissue has specific properties different from the substrates in the Guire patent. The

Carpentier patent does not teach or suggest attaching growth factors to crosslinked tissue. The Tischer patent merely teaches incubation with a vascular endothelial growth factor and not attachment of the vascular endothelial growth factor as in the present invention. The cited patents, alone or combined, do not teach or suggest the invention as claimed in claim 26.

Since the combination of the Guire patent, the Carpentier patent and the Tischer patent does not teach or suggest the claimed invention, Applicants respectfully request the withdrawal of the rejection of claims 9, 10, 14, 15, 21-24 and 26 under 35 U.S.C. § 103(a) as being unpatentable over combination of the Guire patent, the Carpentier patent and the Tischer patent.

CONCLUSIONS

Applicant submits that this application is in condition for allowance, and such action is respectfully requested. The Examiner is invited to telephone the undersigned agent to discuss any questions or comments that the Examiner may have.

The Commissioner is authorized to charge any fee deficiency required by this paper or credit any overpayment to Deposit Account No. 23-1123.

Respectfully submitted,

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